European Food Safety Authority; Outcome of the Public Consultation on the Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition, and Allergies (NDA) on establishing Food-Based Dietary Guidelines

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SCIENTIFIC REPORT OF EFSA

Outcome of the Public Consultation on the Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition, and Allergies (NDA) on establishing Food-Based Dietary Guidelines[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

On 2 July 2008, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) endorsed a draft Opinion on Food-Based Dietary Guidelines to be released for public consultation. This Scientific Report summarises the comments received through the public consultation and outlines how these were taken into account in the final opinion.

EFSA had received 60 contributions from 19 interested parties (individuals, non-governmental organisations, industry organisations, academia and national assessment bodies). After a meeting with national experts on Dietary Reference Values which was held in September 2009, three additional comments on the draft Opinion on Food-Based Dietary Guidelines were received from three Member States.

The main comments which were received during the public consultation related to: the addition of water in the list of dietary components listed for the identification of diet-health relationships, possible adverse health effects of excessive consumption of sugar(s), sugar-sweetened beverages, the performance of risk-benefit analysis, the contribution of food supplements and fortified food as nutrient sources in the diet, and to the section on implementation /communication /evaluation of food-based dietary guidelines.

All the public comments received and comments from Member States that related to the remit of EFSA were assessed and the Opinion on Food-Based Dietary Guidelines has been revised taking relevant comments into consideration.

1 On request from EFSA, Question No EFSA-Q-2009-00922, issued on 01 March 2010.

2 Correspondence: NDA@efsa.europa.eu

3 Acknowledgement: EFSA wishes to thank the members of the Working Group on Population Reference Intakes for the preparation of this EFSA scientific output: Carlo Agostoni, Jean-Louis Bresson, Jean-Michel Chardigny, Susan Fairweather-Tait, Albert Flynn, Ambroise Martin, Monika Neuhäuser-Berthold, Hildegard Przyrembel, John Joseph Strain, Inge Tetens, Daniel Tomé and EFSA's staff member Silvia Valtueña Martínez for the support provided to this EFSA scientific output.

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BACKGROUND

On 2 July 2008, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) endorsed a draft Opinion on Food-Based Dietary Guidelines to be released for public consultation.

The scientific advice on nutrient intakes is important as the basis of Community action in the field of nutrition; for example such advice has in the past been used as the basis of nutrition labelling. The Scientific Committee on Food (SCF) report on nutrient and energy intakes for the European Community dates from 1993.

The European Commission has asked EFSA to review and if necessary update such advice to ensure that the Community action in the area of nutrition is underpinned by the latest scientific advice. To this end the EFSA has been requested to consider the existing Population Reference Intakes for nutrients and certain other dietary components.

Furthermore, and in order to communicate effectively on nutrition and healthy diets to the public at large, it is generally more appropriate to express recommendations for the intake of individual nutrients or substances in food-based terms. To this end EFSA has been also asked by the European Commission to provide assistance on the translation of nutrient based dietary recommendations for a healthy diet into food-based recommendations intended for the European population as a whole.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders on its work, EFSA engages in public consultations on key issues. The work on Dietary Reference Values including food-based dietary guidelines is considered to be such an issue. Accordingly, the draft Opinion on Food-Based Dietary Guidelines was released for public consultation for four months (from 8 August until 15 December 2008) on the EFSA website[4]. Stakeholders were informed and invited to submit comments.

Together with other draft Opinions on Dietary Reference Values, the draft Opinion on Food-Based Dietary Guidelines was also discussed on a National Expert Meeting with Member States on Dietary Reference Values held in Barcelona on 7 and 8 September 2009, with a deadline for written comments by 30 September 2009.

EFSA has committed to publish the comments received during the public consultation as well as a short report on the outcome of the consultation, taking also into account comments received by Member States in the commenting period after the National Expert Meeting.

COMMENTS RECEIVED

At the end of the public consultation period in December 2008 EFSA had received 60 contributions from 19 interested parties (individuals, non-governmental organisations, industry organisations, academia and national assessment bodies). After the National Expert Meeting on Dietary Reference Values in September 2009, three additional comments on the draft Opinion on Food-Based Dietary Guidelines were received from three Member States. All comments received were scrutinised by the NDA secretariat and subsequently compiled with reference to the contributor and the section of the draft opinion to which the comment referred (see Appendix). Comments submitted formally on behalf of an organisation appear with the name of the organisation. The comments received by Member States during the National Expert Meeting are published in the minutes of that meeting on the EFSA website.

[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902045161.htm

SCREENING AND EVALUATION OF COMMENTS RECEIVED

1. General comments

In general the comments were constructive and aimed to help improving the draft Opinion. It was noted that several contributions copied or reiterated arguments brought forward already by other organisations.

The majority of the comments supported the general view of the Opinion and of the various sections. Some comments congratulated EFSA for the good quality of the document.

2. Specific comments

The main issues raised in the comments received are summarised by topic below.

Water: Suggestion to add water in the list of dietary components listed for the identification of diet-health relationships

Sugar(s), sugar-sweetened beverages: Some parties proposed to implement the part on sugars with a review of the literature available on the consequences of excessive sugar-sweetened beverage consumption on increased energy intake, overweight and long-term adverse health effects. Conversely, other parties argued that, for instance, the evidence for an association between soft drink consumption and the development of obesity is not strong. There were also conflicting comments with respect to potential adverse health effects of added sugars.

Dietary patterns /food categories /sub-categories /food products /claims: Suggestion to refer to specific food products in the Opinion and to focus more on foods with high and low energy density. Furthermore, links were made between FBDG, health claims and nutrient profiles. The role of labelling and logos was mentioned as one of the possibilities to enhance the impact of FBDG.

Risk-benefit analysis: Suggestion to consider the assessment of risk of contaminant exposure from certain foods and include the approach of benefit-risk analysis.

Food supplements: Suggestions to consider also the intake/contribution of food supplements and fortified foods as nutrient sources.

Process-related comments: Suggestions related to the weighing of the evidence, to the inclusion of a step for defining the first draft of FBDG, and to the inclusion of field testing of FBDG.

Implementation /communication /evaluation: Suggestions to have more guidance regarding the implementation, monitoring and evaluation of FBDG. The need for careful evaluation of FBDG after implementation and the need to consider dietary intervention studies were stressed. Also evaluation of barriers to a healthy diet was recommended.

Conclusion: Several comments fully agreed upon the conclusion that it is not feasible to establish detailed and effective FBDG which could be used at the European level. In addition some comments suggested stressing also those parts of FBDG that are clearly universal.

INCORPORATION OF THE COMMENTS IN THE OPINION

The EFSA NDA Working group on Population Reference Intakes (PRI) was presented with the compilation of comments and discussed them at a dedicated meeting. Many of the comments were appropriate and aimed to enhance the scientific quality and clarity of the document. These comments were taken into account and the document was revised accordingly as follows:

Water: Water has been added to the list of foods and nutrients listed for the identification of diet-health relationships. Also, explicit reference to food components that modify the energy density of foods has been included in relation to energy balance.

Sugar(s), sugar-sweetened beverages: This Opinion was not meant to deal with the health effects of sugars or sugar-containing foods specifically. The health effects of sugars and sugar-containing foods are dealt with in the Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre.

Dietary patterns /food categories /sub-categories /food products /claims:

Risk-benefit analysis: Acknowledgement has been made to the fact that the nutritional and health benefits associated to the intake of certain foods or food constituents for the general population could be associated with potential health risks for certain population subgroups, and that the benefit-risk analysis to address this issue should be country specific.

Food supplements: The contribution of food supplements and fortified foods as nutrient sources has been acknowledged in the Opinion.

Process-related comments: A comment on the differences between the basis for establishing Dietary Reference Values for nutrients and the basis for establishing nutrient recommendations has been added to the introduction.

Implementation /communication /evaluation: Consumer behaviour has been added to the elements to be taken into account on the evaluation of the impact of FBDG. Reference has been made in section 4.3 (identification of nutrients of public health importance) to dietary guidelines when evaluating the nutritional adequacy of diets, to a recently developed example from the Netherlands on how this can be done, and to the fact that desirable and attainable nutrient intake targets to be achieved at a population level could be set either for the general population or for specific population subgroups. Finally, mention has been made to the specific nutrients that may be consumed above or below current recommendations across Europe and to the need of focusing on foods providing (or not containing) such nutrients in significant amounts in order to set country-specific FBDG.

EFSA wishes to thank all stakeholders for their contribution.

GLOSSARY / ABBREVIATION

DRV	Dietary Reference Values
EFSA	European Food Safety Authority
FBDG	Food-based Dietary Guidelines

APPENDIX

COMMENTS RECEIVED ON THE DRAFT OPINION RELATED TO FOOD-BASED DIETARY GUIDELINES DURING THE PUBLIC CONSULTATION PERIOD

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
British Nutrition Foundation	Conclusions and recommendations	Dear Sir, The British Nutrition Foundation (BNF) is a not-for-profit organisation with charitable status that promotes the wellbeing of society through the impartial interpretation and effective dissemination of scientifically based knowledge and advice on the relationship between diet, physical activity and health. It works in partnership with academic and research institutes, the food industry, educators and government. Comments on the consultation on the EFSA drafts for food-based dietary guidelines The British Nutrition Foundation (BNF) is pleased to have the opportunity to comment on the draft document, discussing the development of Food-Based Dietary Guidelines (FBDG), as prepared by the EFSA Panel on Dietetic Products, Nutrition and Allergies. BNF has read the Panel's proposal with considerable interest. We think that the panel has generated a valuable document, which will be a good basis for the development of FBDG, and we generally agree with the suggestions made in this document. We would like to emphasise that BNF shares the opinion that FBDG are important to communicate nutritional needs to the public. Compared to nutrient based guidelines, they can be easy to understand and easy to follow, if presented in a clear and simple way. We also agree that FBDG should be established by country or region rather than in a pan-European manner. They should also reflect the foods and dietary habits that are typical for the respective country or region. European-wide FBDG could reduce the relevance of the recommendations to an individual, because they may not be representative of the foods that are available in their particular region or country. Also, taking a pan-European approach would not allow the opportunity to focus on nutrient problems specific to a particular region, which can vary from country to country. However, we suggest that more emphasis is placed on the consideration of the implementation of FBDG to ensure that the messages are delivered to the relevant population groups. If the FBDG are established, yet the messages are not adequately conveyed to the public, we would have little impact on improving the diet of a population. We think that this implementation step should be considered in more detail to ensure that FBDG will be an effective tool for

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		delivering relevant health messages. BNF agrees that monitoring and evaluation of the effects of FBDG is crucial in order to identify possible weaknesses of FBDG or their implementation. Researchers working on the EU-funded EuroFIR project, in which BNF is actively involved, are collating information about traditional dietary patterns in European Member States to gain a better understanding of the role they play in providing nutrients to the local population. Such information may be of use to the Panel when local FBDG are being established. Yours thankfully, Prof. Judith Buttriss Director General, The British Nutrition Foundation. Dr. Elisabeth Weichselbaum Nutrition Scientist, The British Nutrition Foundation.
CEFS (Comité Européen des Fabricants de Sucre)	4. Scientific process in setting FBDG	Sugars - Line 388 The frequent consumption of all fermentable carbohydrates – not only sugars, but also starches – contributes to an increased risk of dental caries [van Loveren, C, Ernährung und Zahnkaries, Oralprophylaxe & Kinderzahnheilkunde, Vol. 28, Nr. 2, 2006, p. 76-81 // Wiedemann W., Kohlenhydrate, Karies und die Erkrankungen des Zahnhalteapparates, in: Kohlenhydrate in der Ernährungsmedizin unter besonderer Berücksichtigung des Zuckers, Hrsg. Kluthe R, Kasper H, Aktuelle Ernährungsmedizin 1997 (Suppl), S. 54-59 // König KG, Navia JM, Nutritional role of sugars in oral health, Am J Clin Nutr 1995, 62 (Suppl) S. 275-283]. General Comment: The relationship with dental caries is ascribed here in this draft Opinion only to sucrose, glucose and fructose as nutrients and to sweets, confectionery products and sugar-containing drinks as foods. However dental research has shown that not only sugars and sweet tasting foods are cariogenic, but also carbohydrate staple foods, like e.g. bread and savoury products. The description of the health relationship of nutrients and foods with respect to dental caries does not provide the full picture experts have agreed upon, as it is the frequency of intake of all carbohydrate-containing foods and beverages, thus of all fermentable carbohydrates, that constitute the risk (König, 2000).

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		Lingström et al. (1993) have shown that acid formation in plaque after chewing soft bread or potato chips is more intense and lasts longer than after intake of sucrose. Also fruits should be included in the list of foods. We also wonder why lactose has not been mentioned in the list of cariogenic sugars, as paediatric dentists advocate not putting babies to bed with a bottle of milk. Furthermore, the risk of caries can be minimised by regular oral hygiene and the use of fluoridated toothpaste. As epidemiological surveys demonstrate, caries among the young generation have declined tremendously; Western European countries now show a low level of caries with an increasing proportion of children having a cavity-free dentition. Literature: König K.G.: Diet and oral health, Int Dent J. (2000) 50; 162-174 Lingström P, Imfeld T, Birkhed D.: Comparison of three different methods for measurement of plaque-pH in humans after consumption of soft bread and potato chips. J. Dent. Res. 1993; 72: 865-870 Micheelis M, Schiffner U (Eds): Vierte Deutsche Mundgesundheitsstudie / Fourth German Oral Health Study (DMS IV). Institut der Deutschen Zahnärzte (IDZ), Deutscher Zahnärzteverlag DÄV, Köln 2006 WHO Oral Health Country/Area Profile Programme (CAPP): http://www.whocollab.od.mah.se/euro.html
CEFS (Comité Européen des Fabricants de Sucre)	4. Scientific process in setting FBDG	Sugars - Line 398 The statement that there is some evidence that sugar-sweetened beverages do not induce satiety to the same extent as solid forms of carbohydrate and that high intakes of sugars in the form of sugar-sweetened beverages might contribute to weight gain, is controversial. Several studies have investigated the possible association between soft drinks consumption and weight gain and obesity. The most recent quantitative meta-analysis and qualitative review on the topic of sugar-sweetened beverages and weight gain in children and adolescents, based on ten longitudinal studies and two randomized controlled trial studies found that the association between soft drink consumption and BMI was near zero [Forshee RA, Anderson PA,

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		Storey ML, Sugar-sweetened beverages and body mass index in children and adolescents: a meta-analysis, Am J Clin Nutr 2008;87:1662–71]. No evidence for an association between sugar-sweetened beverage consumption at the age of 5 or 7 and fatness at the age of 9 was found in a cohort of British children (Johnson L, Mander AP, Jones LR, Emmett PM, Jebb SA: Is sugar sweetened beverage consumption associated with increased fatness in children? Nutrition (2007) 23: 557-563). A recent systematic review of 4 proposed mechanisms that could explain a link between soft drinks and obesity (excess calorie intake; glycaemic index and glycaemic load; lack of effect of liquid calories on satiety; and displacement of milk) concluded that current evidence is inconclusive [Bachman CM, Baranowski T, Nicklas TA, Is there an association between sweetened beverages and adiposity? Nutr. Rev.2006- 64:153-74]. The notion that sugar-sweetened beverages do not induce satiety to the same extent as solid forms of carbohydrate is controversial, as a sugar-sweetened beverage and cookies suppressed hunger ratings equally and no temporal difference in satiety was observed. When it comes to energy compensation, the occasion of consumption may be more important than the physical form (solid or liquid) in which the food is consumed [Almiron-Roig E, Flores SY, Drewnowski A., No difference in satiety or in subsequent energy intakes between a beverage and a solid food, Physiol Behav. 2004; 82(4): 671-677]. This has also been underlined in a review by Anderson, which concludes that sugars in solution reduce subsequent food intake to an extent that depends both on the quantity of sugars consumed and on the time interval before the next meal [Anderson GH., Sugars-containing beverages and post-prandial satiety and food intake, Int J Obes 2006; 30: S52-S59]. Further studies compared the satiating effects of a sucrose-sweetened beverage with those of isoenergetic drinks (soft drinks, juice and 1% fat milk) and could not find any difference in terms of satiety and energy compensation [Soenen S, Westerterp-Platenga MS, No differences in satiety or energy intake after high-fructose-corn syrup, sucrose or milk preloads, Am J Clin Nutr. 2007; 86: 1586-1594 // Drewnowski A, Bellisle F, Liquid calories, sugar, and body weight, Am J Clin Nutr. 2007; 85: 651-661]. It was highlighted in a review by Pereira that many studies on soft drinks were poorly designed and the results were not consistent. Pereira also noted the lack of high-quality intervention studies. There are also technical difficulties in assessing whether individual components of the diet may be responsible for obesity, or whether obesity simply results from a general over-consumption of all dietary sources of energy [Pereira MA., The possible role of sugar-sweetened beverages in obesity: a review of the evidence, Int J Obes 2006; 30: S28-S36].

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		Considering the above, it seems that evidence to date of any link between soft drinks and obesity or weight gain is equivocal.
Coldiretti (COPA COGECA member)	3. General principles for establishing FBDG	Section "General Principles" (3 par.) 311-313 • The ability of FBDGs to promote changes in the diet should be monitored better, evaluating for instance the barriers to a healthy diet, and not only –as suggested by the Draft Opinion of EFSA- the cost-benefit ratio ("cost-effectiveness", in the Guidance Document). In itself, cost-benefit analysis can lead to a simple abandoning of the programme, without learning lessons from the experience carried out. • Furthermore, it would be very useful to share the information provided by the National agencies about FBDGs: it is very interesting to know how many FBDGS are addressed to subgroups, or on the contrary, to the population in general (as should be, considering the first goal of FBGDs. Section "General Principles" (3 par.) 314-317 FBDG, in order to be: -socially and culturally acceptable, -useful for nutritional and health purposes; should pay attention to: - the respect of seasonality of foodstuffs, with particular regard to fresh food (i.e, F&V), and don't encourage the consumption of foods out-of-season, with treatment agents; - the freshness in itself of foods with time-dependent nutritional decadence (i.e. vitamins) - FBDG which wouldn't consider such features, could unbalance dietary patterns established among people. • In this direction is very meaningful the suggestion of EFSA to have generally established FBDG for the whole european population on certain food categories, leaving the detail on single food items to National Agencies.
Coldiretti (member of COPA COGECA member)	4. Scientific process in setting FBDG	Section "Scientific Principles" (par. 4.4) – 538-542- • Food categories which are consistent with the scope of general Guidelines could be: cereals, diary products, f&v, fish, meat • The "alcoholic" category" is too wide to obtain useful scientific assessment (includes both super-alcoholics and wine/beer

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Coldiretti (member of COPA COGECA member)	4. Scientific process in setting FBDG	Section "Scientific Process" (4 par.) -332 and forth- • In its draft Opinion, EFSA seems to confirm the link between nutrients and diseases (v. par. 4.1), relevant for individuals, but also at epidemiological level for groups/sub-groups. • Supporting the development of FBDGs at the national level, EFSA recognizes that a causal association nutrients/diseases is strong enough to require a particularistic, country-based approach. • Despite of that, the choice of establish an intellectual property protection framework for Health Claims in Europe (art. 14 and 13.5 of reg. CE 1924/2006) doesn't allow FBDGs to show effects of reduction of the risk(s) associated to diseases. • A possible, undesireble effect on public health arises from the privatisation of information with public health relevance. • The real risk is to deter national citizenship from healthy foods. Moreover the resulting increase of consumption of claim-bearing-foods could affect a balanced diet. • If well stated FBDGs not only could ease the consumption of foods which can be under-consumed (ie, f&v), but also limit that of food at risk of over-consumption. • To this purposes, to state for instance that " 3 diary products a week contribute to a healthy body" is a message that can be reasonably addressed to anybody, even to those at risk of over-consumption of diary products. 1. FBDG should be able to make reference to dietary patterns as a whole (i.e., the Mediterranean Diet) 2. Dietary patterns are moreover at the centre of on going studies confirming the causal association with the prevention of chronic diseases. Since there are several diets/food patterns able to achieve the goal of a healthy lifestyle, the unique limit for FBDG to make claims could be that of avoiding comparative statements against other diets/food patterns. 3. It would be very useful to have FBDGs stressing the link with health conditions, when no ex art. 13 (reg. 1924/2006) generic claims have been submitted by national authorities. 4. To include messages about risk prevention of developing diseases (formally, ex art. 14 /reg.1924 claims), -but referred

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		to dietary patterns/food categories- if enough evidence is available, is an important public health goal. In such a case, the focus should be on food categories /diets more than on single food items. The case of fruit and vegetables vs cardiovascular diseases is emblematic for our purpose.
Coldiretti (member of COPA COGECA member)	5. Implementation and evaluation of FBDG	Section "Implementation" (par. 5) • A problem arising from the country-based approach suggested by EFSA, could be the fragmentation of the internal market as a possible barrier to the free circulation of goods. • If considered necessary, to limit the consequences of such a problem, it could be tested a system of shared FBDGs among areas of 2 or more countries, similar by intake of nutrients relevant to the health status. (i.e., France and Belgium, Sweden and Finland, etc), as suggested by Custer Analysis and Principal Component Analysis on major nutrients. Harmonization with possible national labelling on nutritional content (i.e., traffic light or others as foreseen in the draft regulation of the EC) is necessary, in order not to give consumers misleading messages. A framework is required in our opinion to deal with that and to have a common internal food policy on consumers information.
Coldiretti (member of COPA COGECA member)	5. Implementation and evaluation of FBDG	Section "Implementation" (par. 5.1.1) 808-811 and 812-816 • FBDGs should be able to receive crossed country-european founding, in order to be developed, "out of the label" and/or "in store" as far as they accomplish with the maintenance of health in the UE. Labeling is only a measure to inform consumers, more actions are required. • FBDGs are an unique tool to promote healthy foods otherwise not advertised by private companies. • This way, FBDGs can be considered as an instrument of public policy to rebalance the enormous power of advertising on processed foodstuffs of low nutritional value but with high energy density. • It is coherent with CE recent intentions about health, obesity and well being (White and Green Book related to healthy lifestyles and diets), not only programmes, but also actions (Eu platform)

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Copa-Cogeca foodstuffs working group	3. General principles for establishing FBDG	General Principles (3 par.) 306-310 Coldiretti and COPA-COGECA (?) request a Stakeholders' Platform session to discuss FBDG and to feed input into EFSA. Section "General Principles" (3 par.) 311-313 • The ability of FBDGs to promote changes in the diet should be monitored better, evaluating for instance the barriers to a healthy diet, and not only –as suggested by the Draft Opinion of EFSA- the cost-benefit ratio ("cost-effectiveness", in the Guidance Document). In itself, cost-benefit analysis can lead to a simple abandoning of the programme, without learning lessons from the experience carried out. • Furthermore, it would be very useful to share the information provided by the National agencies about FBDGs: it is very interesting to know how many FBDGS are addressed to subgroups, or on the contrary, to the population in general (as should be, considering the first goal of FBGDs. Section "General Principles" (3 par.) 314-317 FBDG, in order to be: -socially and culturally acceptable, -useful for nutritional and health purposes; should pay attention to: - the respect of seasonality of foodstuffs, with particolar renard to fresh food (i.e, F&V), and don't encourage the consumption of foods out-of-season, with tractant agents; - the freshness in itself of foods with time-dependent nutritional decadence (i.e. vitamins) - FBDG which wouldn't consider such features, could unbalance dietary patterns established among people. • In this direction is very meaningful the suggestion of EFSA to have generally established FBDG for the whole european population on certain food categories, leaving the detail on single food items to National Agencies.

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Copa-Cogeca foodstuffs working group	4. Scientific process in setting FBDG	Section "Scientific Process" (4 par.) -332 and next- • In its draft Opinion, EFSA seems to confirm the link between nutrients and diseases (v. par. 4.1), relevant for individuals, but also at epidemiological level for groups/sub-groups. • Supporting the development of FBDGs at the national level, EFSA recognizes that a causal association nutrients/diseases is strong enough to require a particularistic, country-based approach. • Despite of that, the choice of establish an intellectual property protection framework for Health Claims in Europe (art. 14 and 13.5 of reg. CE 1924/2006) doesn't allow FBDGs to show effects of reduction of the risk(s) associated to diseases. • A possible, undesireble effect on public health arises from the privatisation of information with public health relevance. • The real risk is to deter national citizenship from healthy foods. Moreover the resulting increase of consumption of claim-bearing-foods could affect a balanced diet. • If well stated FBDGs not only could ease the consumption of foods which can be under-consumed (ie, fruit & vegetables), but also limit that of food at risk of over-consumption. • To this purposes, to state for instance that " 3 diary products a week contribute to a healthy body" is a message that can be reasonably addressed to anybody, even to those at risk of over-consumption of diary products. 1. FBDG should be able to make reference to dietary patterns as a whole, like the Mediterranean Diet 2. The Mediterranean Diet is moreover at the centre of on going studies confirming the causal association with the prevention of chronic diseases. Since there are several diets/food patterns able to achieve the goal of a healthy lifestyle, the unique limit for FBDG to make claims could be that of avoiding comparative statements against other diets/food patterns. 3. It would be very useful to have FBDGs stressing the link with health conditions, when no ex art. 13 (reg. 1924/2006) generic claims have been submitted by national authorities. To include risk prevention of developing diseases, if enough evidence is available, is an important public health goal. In

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		such a case, the focus should be on food categories /diets more than on single food items. The case of fruit and vegetables vs cardiovascular diseases is emblematic for our purpose. Section "Scientific Principles" (par. 4.4) – 538-542 • Food categories which are consistent with the scope of generale Guidelines could be: cereals, diary products, f&v, fish, meat • The "alcoholic" category" is too wide to obtain useful scientific assessment (includes both super-alcoholics and wine/beer).
Copa-Cogeca foodstuffs working group	5. Implementation and evaluation of FBDG	Section "Implementation" (par. 5.1.1) 808-811 and 812-816 • FBDGs should be able to receive crossed country-european founding, in order to be developed, "out of the label" and/or "in store" as far as they accomplish with the maintenance of health in the UE. Labeling is only a measure to inform consumers, more actions are required. • FBDGs are an unique tool to promote healthy foods otherwise not advertised by private companies. • This way, FBDGs can be considered as an instrument of public policy to rebalance the enormous power of advertising on processed foodstuffs of low nutritional value but with high energy density. • It is coherent with CE recent intentions about health, obesity and well being (White and Green Book related to healthy lifestyles and diets), not only programmes, but also actions (Eu platform) Section "Implementation" (par. 5) • A problem arising from the country-based approach suggested by EFSA, could be the fragmentation of the internal market as a possible barrier to the free circulation of goods. • To limit the consequences of such a problem, it could be tested a system of shared FBDGs among areas of 2 or more countries, similar by intake of nutrients relevant to the health status. (i.e., France and Belgium, Sweden and Finland, etc), as suggested by cluster analysis and Principal Component Analysis on major nutrients.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Danone Research	1. Introduction	Page 5 Line 158: water is not included in the list of the macronutrient and dietary component on which EFSA is asked to provide advice on. DANONE RESEARCH proposes to include water in the scope of the document as it is an essential requirement for life and quantitatively one of the main nutrients ingested.
Danone Research	4. Scientific process in setting FBDG	Page 10 Line 332: DANONE RESEARCH proposes to include a part on water underlying the key role of adequate water intake on health for two main reasons: firstly, the potential health consequences of dehydration as developed in to the EFSA document "Dietary reference values for water" (Question No EFSA-Q-2005-015a) and secondly, the benefit of increasing pure water intake to the expense of energy intake from other beverages and consequently on the reduction of overweight as demonstrated by Stookey et al., 2007 and 2008.
Danone Research	4. Scientific process in setting FBDG	Page 11 Line 388: DANONE RESEARCH proposes to implement the part on sugars with a review of the extensive literature demonstrating the consequences of excessive sugar sweetened beverages consumption on excess energy intake, overweight and long term health consequences; (Dennison et al., 1997, Ludwig et al. 2001, Forshee and Storey, 2003, Gillis and Bar-Or, 2003, Apovian, 2004, Ariza et al., 2004, Berkey et al., 2004, Philips et al., 2004, Nicklas et al., 2004, Yoo et al., 2004, Davis et al., 2005, Schulze et al., 2005, Welsh et al., 2005, Malik et al., 2006, O'Connor et al., 2006, Paynter et al., 2006, Striegel-Moore et al., 2006, Tam et al., 2006, Ventura et al., 2006, Warner et al., 2006, Dhingra et al., 2007, Dubois et al., 2007, Montonen et al., 2007, Ochoa et al., 2007, Sanigorski et al., 2007, Bazzano et al., 2008, Libuda et al. 2008, Lutsey et al., 2008, Forshee et al., 2008, Mac Naughton et al., 2008 Palmer et al., 2008). This part should also be supported by the recent high quality interventional studies (Ebbeling et al., 2006, Taylor at al., 2007 and Sichieri et al., 2008)
Danone Research	4. Scientific process in setting FBDG	Page 15,ligne 544 The aim of this paragraph is to present the average nutrient intake contributions of different foods by categorizing them into food groups. Please note that a given food category may contain sub-categories with distinct nutritional differences. Using the "milk and milk products" category as an example, Saturated Fatty Acid (SFA) content varies between subcategories: indeed, whole milk, plain whole milk yoghurt, ice-cream, cream and cheddar cheese have respectively 2.14g, 2.22g, 7.14g,12.6g and 21.3g of SFA per 100g of product (Data extracted from CIQUAL- 2008 online edition - http://www.afssa.fr/TableCIQUAL).

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Dept of Clinical Nutrition/University of Gothenburg	Conclusions and recommendations	1. We fully agree upon the Panels conclusion that it is not feasible to establish detailed and effective FBDG which could be used at the EU level, mainly due to wide disparities in dietary/cultural habits and the availability of food products between Member states. 2. We miss a discussion regarding the possibility that environmental issues could be taken into account producing FBDG 3. Regarding the part about alcohol (line 421-431) we miss a broader risk analysis. We lack information regarding trafic accidents due to alcohol use, violence/injuries and chirrosis. Best regards from a group of scientists at Dept of Clinical Nutrition, Sahlgrenska Academy, University of Gothenburg
EUROPEAN FEDERATION OF BOTTLED WATER	1. Introduction	Section Terms of reference as provided by EC, page 6, lines 158-162 Water is not included in the list of dietary components, for which ESFA is requested to advice. Water is a macronutrient and is essential for all functions of the body. Water is essential for health and life. EFBW proposes to include "Water as a dietary component" in the list of dietary components to be advised. In addition several health programs implemented in various Member States have already mentioned the critical role in human nutrition as an essential nutrient.
EUROPEAN FEDERATION OF BOTTLED WATER	4. Scientific process in setting FBDG	Section 4.1 Identification of diet-health relationships, page 11, line 333 EFBW suggests adding that "a water intake which balances losses and thereby assures adequate hydration of the body tissues is essential for health and life". ("Dietary reference values for water – Question n°EFSA-Q-2005-015a, page 1, lines 20-21) EFBW recommends to precise the health consequences of dehydration, as developed by EFSA ("Dietary reference values for water – Question n°EFSA-Q-2005-015a, page 1, lines 28-30): "without compensation and further increases of losses of body water, reductions in physical and cognitive performance, in thermoregulation and cardiovascular function occur. A loss of 10% or more of body water can be fatal"
EUROPEAN FEDERATION OF BOTTLED WATER	4. Scientific process in setting FBDG	Section 4.1 Identification of diet-health relationships, page 11, line 397 EFSA's draft states that "high intakes of sugars in the form of sugar-sweetened beverages might contribute to weight gain (van Dam and Seidell, 2007; Mann et al., 2007)". The effect or consequences beyond hydration of some beverages regarding their long term potential consequences on health should be reviewed. EFBW would recommend considering the case of sugar in the form of some beverages, when consumed in excess, for their effects on energy intake. 1 Popkin et al. Am J Clin Nutr. 2006; 83: 529-542

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		2 WHO, 2007. The challenge of obesity in the WHO European Region and the strategies for response 3 Ludwig et al. Lancet. 2001; 357, 505-508 4 Dennison et al. Pediatrics. 1997; 99, 15-22 5 Forshee et al. Int J Food Sci Nutr. 2003; 54, 297-307 6 Gillis et al. J Am Coll Nutr. 2003; 22, 539-545 7 Apovian, C.M. JAMA. 2004; 292, 978-979 8 Ariza et al. J Urban Health. 2004 ; 81, 150-161 9 Berkey et al. Obes Res. 2004 ; 12, 778-788 10 Phillips et al. Obes Res. 2004 ; 12, 461-472 11 Nicklas et al. J Am Diet Assoc. 2004 ; 104, 1127-1140 12 Welsh et al. Pediatrics. 2005; 115, e223-229 13 Malik et al. Am J Clin Nutr. 2006; 84, 274-288 14 O"Connor et al. Pediatrics. 2006; 118, e1010-1018 15 Striegel-Moore et al. J Pediatr. 2006; 148, 183-187 16 Tam et al. Int J Obes. 2006; 30, 1091-1093 17 Warner et al. Obesity. 2006; 14, 1966-1974 18 Dubois et al. J Am Diet Assoc. 2007; 107, 924-934 19 Ochoa et al. Nutrition. 2007; 23, 379-384 20 Sanigorski et al. Public Health Nutr. 2007; 10, 152-157 21 Libuda et al. Br J Nutr. 2008; 99, 1370-1379 22 Forshee et al. Am J Clin Nutr. 2008; 87, 1662-1671 23 Ebbeling et al. Pediatrics. 2006; 117, 673-680 24 Taylor et al. Am J Clin Nutr. 2007; 86, 735-742 25 Sichieri et al. Public Health Nutr. 2008; 1-6 26 Stookey et al. Obesity 2008; 10: 1038-1045 27 McNaughton et al. Diabetes Care. 2008; 31, 1343-1348 28 Schulze et al. Am J Clin Nutr. 2005; 82, 675-684; quiz 714-675 29Paynter et al. Am J Epidemiol. 2006; 164, 1075-1084 30 Montonen et al. J Nutr. 2007; 137, 1447-1454 31 Bazzano et al. Diabetes Care. 2008; 31, 1311-1317 32 Palmer et al. Arch Intern Med. 2008; 168, 1487-1492 33 Yoo et al. Am J Clin Nutr. 2004; 80, 841-848 34 Davis et al. Am J Clin Nutr. 2005; 82, 1004-1010 35 Ventura et al. Pediatrics. 2006 ; 118, 2434-2442 36 Dhingra et al. Circulation. 2007; 116, 480-488 37 Lutsey et al. Hum Exp Toxicol. 1994; 13, 393-399

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Health Council of the Netherlands	3. General principles for establishing FBDG	lines 264-268 and 303-305 Judging the evidence: The value of different study designs is discussed. We suggest to add the levels of scientific evidence of different study types and the implication for the weighing of the evidence and the setting of food-based dietary guidelines.
Health Council of the Netherlands	4. Scientific process in setting FBDG	Lines 324-331 Weighing the evidence: The scientific evidence on diet-health relationships could be assessed at a European level. We agree that setting food-based dietary guidelines is a country-specific activity, to some extent because there are some differences in diet-related health problems between European countries, but mainly because of the fact that cultural differences should influence the translation of dietary guidelines to the level of food products.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
IMACE	4. Scientific process in setting FBDG	Chapter : 4. Scientific process in setting FBDG Line : 378 Thus, a good dietary strategy to reduce the risk of cardiovascular disease is to replace foods high in SFA and TFA with foods high in PUFA and MUFA. A good example is a switch from butter to soft margarine. A review by Zock and Katan (1997) of dietary intervention studies where butter in the diet was replaced by soft margarine, as well as several such studies published since (Cleghorn 2003, Kozlowska-Wojciechowska 2003, Hendriks 1999, Judd 1998) show that LDL-cholesterol is consistently higher on butter diets. Switching from butter to soft margarine resulted in significant LDL-cholesterol lowering in these studies. References: Cleghorn CL, Skeaff CM, Mann J, Chisholm A. Plant sterol-enriched spread enhances the cholesterol-lowering potential of a fat-reduced diet. Eur J Clin Nutr 2003;57:170-76. Hendriks HFJ, Weststrate JA, van Vliet T, Meijer GW. Spreads enriched with three different levels of vegetable oil sterols and the degree of cholesterol lowering in normocholesterolaemic and mildly hypercholesterolaemic subjects. Eur J Clin Nutr 1999;53:319-27. Judd JT, Baer DJ, Clevidence BA, Muesing RA, Chen SC, Weststrate JA, et al. Effects of margarine compared with those of butter on blood lipid profiles related to cardiovascular disease risk factors in normolipemic adults fed controlled diets. Am J Clin Nutr 1998;68:768-77. Kozlowska-Wojciechowska M, Jastrzebska M, Naruszewicz M, Foltynska A. Impact of margarine enriched with plant strerols on blood lipids, platelet function, and fibrinogen level in young men. Metabolism 2003;52:1373-78. Zock PL, Katan MB. Butter, margarine and serum lipoproteins. Atherosclerosis 1997;131:7-16.
IMACE	4. Scientific process in setting FBDG	Chapter : 4. Scientific process in setting FBDG Line : 735 (after ‘research.’) For example soft margarine with a maximum of 40% fat is classified as a food to use ‘preferably’, whereas butter is classified as a food to use ‘exceptionally’.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
KTL	4. Scientific process in setting FBDG	Line 767, Chapter 4.7. We want to emphasize that graphical representation of the FBDG cannot work without words. Graphical format of dietary guidelines are understandable only in the context of selectivity within food groups. We suggest that the text on line 781 is including "to develop graphical representation and verbal key message…" Line 778. We doubt that it is possible to conclude the best graphical format. But we prefer general guideline in the development of graphical formats and we suggest that time period is included in the text, i.e. daily food basket, meal tray etc.
Martek Biosciences Corporation	4. Scientific process in setting FBDG	The identification of foods relevant for food-based dietary guidelines (FBDG) is a critical step in the process of developing FBDG. In section 4.4.1, lines 598-604, EFSA notes that in the identification of relevant foods special consideration should be made for specific populations with varying nutrient needs. EFSA also notes that at this step several factors should be assessed including country-specific food cooking/processing that may affect nutrient content or bioavailability, food availability and seasonality. Importantly, however, the assessment of risk of contaminant exposure from certain foods should also be considered at this step in the process. This consideration is particularly important in instances where the food health relationship is considered beneficial for the general population but possibly detrimental to specific subpopulations. For example, consumption of fish for protection against cardiovascular disease is widely promoted and fish is included in the existing FBDG of at least 9 Member States (lines 900-901), however, certain fish can make major contributions to dietary exposure to environmental contaminants particularly polychlorinated dibenzodioxin and dibenzofuran, dioxin-like polychlorinated biphenyls, and methylmercury (EFSA, 2005). In contrast, fish also provides one of the most abundant food sources of the omega-3 fatty acid, docosahexaenoic acid (DHA). DHA is the most abundant omega-3 fatty acid in the brain and eyes and is a critical nutrient for their optimal development and function. The methylmercury content of fish is typically not considered to outweigh the cardiovascular benefits associated with fish consumption (Mozafarrian and Rimm, 2006) for the general population. Unfortunately, the greatest susceptibility to the critical contaminants found in fish occurs during fetal and infant development which also represents the period of greatest need for DHA omega-3. Data suggests that for every 1 mcg/g increase in maternal hair mercury content, infant IQ decreases by 0.7 points (Cohen et al., 2005). Consequently, pregnant women are advised to avoid large predatory fish such as albacore tuna and swordfish in an effort to reduce fetal contaminant exposure (EFSA, 2005), however, advisories such as these are often generalized to all fish resulting in a dramatic decrease in the availability of DHA (Oken et al., 2003) at a time of increased need.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		A situation such as this demands the addition of a country-specific assessment of the safety and quality of available foods and a risk-benefit analysis for consumption by vulnerable population subgroups. A possible approach would be the application of risk analysis principles as outlined in the current Codex document Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses. It will also be important that FBDG recognize low-risk food alternatives for meeting the nutrient needs of specific subgroups to include "the contribution of fortified foods and dietary supplements…" as noted in the current draft opinion (lines 603-604). For example, dietary supplements from marine microalgae along with DHA-fortified foods and low-methyl mercury fish can meet both the needs of pregnant and nursing women while providing cardioprotection for the general population. Overall, these observations support EFSA's conclusion that "it is not feasible to establish detailed and effective FBDG which could be used at the EU level" and that country-specific guidelines should be developed in step-wise process, as outlined. Moreover, emphasis should be placed on the establishment/revision of DRVs for critical nutrients rather than on the development of FBDG which may be problematic with regard to practical implementation.
NESTLE WATERS MANAGEMENT & TECHNOLOGY	1. Introduction	Section Terms of reference as provided by EC, page 6, lines 158-162 Water is not included in the list of dietary components, for which ESFA is requested to advice. Water is a macronutrient and is essential for all functions of the body. Water is essential for health and life. NWMT proposes to include "Water as a dietary component" in the list of dietary components to be advised. In addition several health programs implemented in various Member States have already mentioned the critical role in human nutrition as an essential nutrient.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
NESTLE WATERS MANAGEMENT & TECHNOLOGY	4. Scientific process in setting FBDG	Section 4.1 Identification of diet-health relationships, page 11, line 333 NWMT suggests adding that "a water intake which balances losses and thereby assures adequate hydration of the body tissues is essential for health and life". ("Dietary reference values for water – Question n°EFSA-Q-2005-015a, page 1, lines 20-21) NWMT recommends to precise the health consequences of dehydration, as developed by EFSA ("Dietary reference values for water – Question n°EFSA-Q-2005-015a, page 1, lines 28-30): "without compensation and further increases of losses of body water, reductions in physical and cognitive performance, in thermoregulation and cardiovascular function occur. A loss of 10% or more of body water can be fatal" NWMT recommends to precise the benefits of replacing caloric sweetened beverages by drinking water to reduce the energy intake and consequently to help to lose weight (Stookey et al. 2008).

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
NESTLE WATERS MANAGEMENT & TECHNOLOGY	4. Scientific process in setting FBDG	Section 4.1 Identification of diet-health relationships, page 11, line 397 EFSA's draft states that "high intakes of sugars in the form of sugar-sweetened beverages might contribute to weight gain (van Dam and Seidell, 2007; Mann et al., 2007)". Despite some debates still going on, the work done by the scientific community on health consequence of high intakes of sugars in the form of sugar sweetened beverages tends to become massive. From the late 90's until mid-2008 there are more than 150 publications on this subject with 90 publications only during the period from 2007 until mid-2008. The positive relation between the high consumption of these drinks and over-weight, obesity, diabetes, insulin resistance and metabolic syndrome can not be ignored. This has been clearly shown on populations which are heavy consumers like in the USA and Mexico. This has driven the US scientific community to develop a beverage guidance system (Popkin et al. 2006). There is today a growing number of high quality results available on this topic that NWMT would like to recall and highlight. NWMT would recommend considering the case of sugar in the form of sugar sweetened beverages, when consumed in excess, for their effects on energy intake, overweight, obesity since obesity increases the risk of numerous diseases including diabetes and cardiovascular diseases (WHO, 2007). This should be considered particularly for very sensitive or exposed groups of populations like children and adolescents. In children and adolescents, despite existing controversial results from observational studies, the relation between the high intakes of sugar in form of sugar sweetened beverages and excessive weight gain or the risk of obesity has been shown by many authors (Ludwig et al. 2001, Dennison et al. 1997, Forshee et al. 2003, Gillis et al. 2003, Apovian, C.M. 2004, Ariza et al. 2004, Berkey et al. 2004, Phillips et al. 2004, Nicklas et al. 2004, Welsh et al. 2005, Malik et al. 2006, O"Connor et al. 2006, Striegel-Moore et al. 2006, Tam et al. 2006, Warner et al. 2006, Dubois et al. 2007, Ochoa et al. 2007, Sanigorski et al. 2007, Libuda et al. 2008, Forshee et al. 2008) and recent interventional studies (Ebbeling et al. 2006, Taylor et al. 2007, Sichieri et al. 2008). These results showed also that reducing sugar added beverage is an efficient strategy to reduce excessive BMI in children. This possibility has also been demonstrated in adult women. More recently (Stookey et al. 2008) it has been demonstrated that replacing caloric sweetened beverages by drinking water is reducing the energy intake and as a consequence, helps to lose weight. The association between high intakes of sugars in the form of sugar sweetened beverages and weight gain in adults has also been clearly established. Consequently several health programs implemented in various Member States have already promoted water as the preferential source of beverage instead of other kinds of beverages.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
NESTLE WATERS MANAGEMENT & TECHNOLOGY	4. Scientific process in setting FBDG	Section 4.1 Identification of diet-health relationships, page 11, line 403 NWMT would recommend to highlight the positive relation between high intakes of sugars in the form of sugar sweetened beverages and occurrence of diabetes, as it has been well documented through observational studies (Schulze et al. 2005, Paynter et al. 2006, Montonen et al. 2007, Bazzano et al. 2008, Palmer et al. 2008). Furthermore, the observational studies conducted by several authors, despite some discrepancies in results tend to show positive relation between sugar sweetened beverages and insulin resistance as well as metabolic syndrome (Yoo et al. 2004, Davis et al. 2005, Ventura et al. 2006, Dhingra et al. 2007, Lutsey et al. 1994).
NESTLE WATERS MANAGEMENT & TECHNOLOGY	4. Scientific process in setting FBDG	Section 4.1 Identification of diet-health relationships, page 12, line 388-392 NWMT fully supports EFSA Panel: "… the evidence indicates that frequent consumption of sweets and confectionery products and sugar-containing drinks may increase caries risk…". NWMT would recommend to add data from the Food Standard Agency in UK highlighting: ""Fizzy drinks, squashes and juice drinks contain lots of sugar – which means they contain a lot of calories- and very few nutrients. So try to keep these to a minimum. The added sugar they contain can also damage teeth. Drinking fewer sugary drinks is a good way to reduce your energy intake, because you won't be missing out on any nutrients by cutting down on them. This will also be good news for you teeth. Research shows that children and young people in the UK eat too much sugar, and more of it comes from fizzy drinks that any other type of food or drink. Children who have lots of sugary drinks, such as fizzy drinks and squashes, are more likely to be overweight and to put on weight" http://www.eatwell.gov.uk/healthydiet/nutritionessentials/drinks/waterandsoftdrinks/?lang=en

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
RIVM	1. Introduction	-very good report! -In the stepwise approach we propose to make an extra step in between the " identification of food consumption patterns" and the paragraph about " testing and optimising". We propose to add a step in which a first draft of the FBDG is defined. In that paragraph attention can be given to the different options for doing this. For example, by starting with the current food pattern in the population by which the recommendations are met, or by starting with the mean current food pattern and changing the important food groups in the direction of the recommendations, or performing an approach based on regression analyses with an optimal fit of the defined requirements. -What about the intake of nutrients by supplements? -In our view more attention should be given to the distinction between the different subgroups. On what basis do we have to define different subgroups? -In section 4.3 the question arises how the different nutrients/foods can be weighted. Which requirement is more important? Should this be done with ranking the estimated health effects (by modelling)? -In parapraph 4.7 an example of a graph is given (Wilson et all). This graph does not show the FBDG, but in which way these recommendations are met? -We propose to move paragraph 4.7 to Chapter 5. -Should attention be given to the consistency in the FBDG between the different subgroups? For example the consistency in the increase of some food groups by age , or the consistency between girls and boys. -The communication with the stakeholders is now mentioned as step 5. Is that not too late?
safefood	4. Scientific process in setting FBDG	Please note the safefood is an organisation that promotes food safety and nutrition in Northern Ireland and Republic of ireland. It is important to acknowledge in this section that the amount of scientific work that goes into the devlopment of food based guidelines should be weighed up against resources and existing data.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
safefood	4. Scientific process in setting FBDG	Please note the safefood is an organisation that promotes food safety and nutrition in Northern Ireland and Republic of ireland. 757 - safefood welcomes cost as an element to testing and optomising FBDG. Food poverty is a key factor associated with inequalities in dietary behaviour. Data on food poverty on the island of Ireland can be found at www.healthyfoodforall.com 767 - It should be acknowledged that the use of different visuals can be challenging when communicating healthy eating messages across two jurisdictions. safefood have encourtered this on the island of Ireland where the Food Pyramid is used in the Republic of Ireland and the Eatwell Plate is used in Northern Ireland. Rather than one communication across the island of Ireland additional resources have had to be used to ensure messages are consitent with visual FBDG in each jurisdiction.
safefood	5. Implementation and evaluation of FBDG	Please note the safefood is an organisation that promotes food safety and nutrition in Northern Ireland and Republic of ireland. 802-811 - this section mentions that messages should be "practical, comprehensible, simple and eay to remember". safefood would suggest that messages should be "engaging" beacuse weithout engagment the target audience will not listen to the message. A social marketing approach whereby the messages are devloped with input from the target audience is an appropriate way to ensure engagement. 834 - consumer surveys are a very useful tool to monitor if you have reached your target audience. safefood regularly conduct consumer surveys that look at awareness, attitudes and reported behaviour in response to food safety and nutrition messages. We are happy to share our methodology and results.
Syndifrais	4. Scientific process in setting FBDG	Line 544 The aim of this paragraph is to present the average nutrient intake contributions of different foods by categorizing them into food groups. Please note that a given food category may contain sub-categories with distinct nutritional differences. Using the "milk and milk products" category as an example, Saturated Fatty Acid (SFA) content varies between sub-categories: indeed, whole milk, plain whole milk yoghurt, ice-cream, cream and cheddar cheese have respectively 2.14g, 2.22g, 7.14g, 12.6g and 21.3g of SFA per 100g of product (Data extracted from CIQUAL- 2008 online edition - http://www.afssa.fr/TableCIQUAL).

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
UNESDA	1. Introduction	Page 5 (Line 156) EFSA is asked by the EC to "provide advice on energy, macronutrients and dietary fibre. Specifically advice is requested on the following dietary components: Carbohydrates, including sugars; Fats, including saturated fatty acids, poly-unsaturated fatty acids and monounsaturated fatty acids, trans-fatty acids; Protein and Dietary fibre. In addition, EFSA is asked to advise on population reference intakes of micronutrients in the diet and, if considered appropriate, other essential substances with a nutritional or physiological effect in the context of a balanced diet which, when part of an overall healthy lifestyle, contribute to good health through optimal nutrition". However, water is not mentioned, although it is included in the questionnaire sent to the EU Member States to get more information on the availability and the type of food-based dietary guidelines (FDBG). UNESDA believes that if EFSA considers that water and adequate hydration of the body is essential for health and life - and even has drafted an opinion on dietary reference values for water - then water should appear as a dietary component in page 6 of the Opinion.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
UNESDA	4. Scientific process in setting FBDG	Page 11, Line 395 The draft states "… there is some evidence that sugar-sweetened beverages do not induce satiety to the same extent as solid forms of carbohydrate, and that high intakes of sugars in the form of sugar-sweetened beverages might contribute to weight gain (van Dam and Seidell, 2007; Mann et al., 2007)". However, the evidence for an association between soft drink consumption and the development of obesity is not strong. Nonetheless, a mechanism that is intended to support such an association has been proposed: Liquid calories fail to trigger physiological satiety mechanisms that regulate appetite and hence result in increased energy intakes. In this respect, Anderson (2006) argues that the associations between sugar-sweetened beverages and obesity must be viewed as circumstantial because biological plausibility and short-term experimental studies do not support cause and effect conclusions. This conclusion is mainly based on the fact that there is insufficient evidence that sugars in solid form stimulate intake regulatory mechanisms and suppress food intake more than those in commonly consumed beverages. The weight of the evidence is very small. Results from different studies are equivocal, there is a lack of controlled randomised clinical trials designed to prove this hypothesis and, apparently, the quantity and time at which sugars are consumed appears to be more important than the physical forms in which sugars are consumed. References 1. Anderson G. Sugar-containing beverages and post-prandial satiety and food intake. International Journal of Obesity 2006; 30: S52-S59. 2. DiMeglio DP, Mattes RD. Liquid versus solid carbohydrate: effects on food intake and body weight. International Journal of Obesity 2000; 24: 794-800. 3. Almiron-Roig E, Flores S, Drewnowski A. No difference in satiety or in subsequent energy intakes between a beverage and a solid food. Physiology & Behavior 2004; 82: 671-677. 4. Lavin J, French S, Ruxton C, Read N. An investigation on the role of oro-sensory stimulation in sugar satiety. International Journal of Obesity 2002; 26: 384-388.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
UNESDA	Conclusions and recommendations	Page 25, Line 919 Conclusions and Recommendations. Public health policies related to diet should implement FBDG for improvement of food consumption patterns for well-being, long-term health of individuals and populations and thus for health cost savings. FBDG will be one of the tools to help reach these goals, but these FBDG have to be tightly linked to recommendations aiming to improve lifestyle patterns, with particular attention on physical activity. General comment The EFSA opinion on nutrient profiles states that "… the setting of nutrient profiles should take into account dietary recommendations, public health considerations, generally accepted scientific evidence relative to the relationship between diet, nutrition and health as well as other considerations of an industrial/commercial, cultural and dietary/culinary nature". The setting of nutrient profiles should also take into account the dietary role and importance of food groups and their contribution of nutrients to the overall diet of the population. However, there are wide disparities in dietary/cultural habits and availability of food products between EU Member States. At the same time, the 1924/2006 regulation requires that the variability of dietary habits and traditions in the EU be taken into account in establishing nutrient profiles. The EC has requested EFSA to provide guidance on the translation of nutrient- based dietary advice into guidance, intended for the European population as a whole, on the contribution of different foods or food groups to an overall diet that would help to maintain good health through optimal nutrition (food based dietary guidelines). Taking into account that: • Foods make up diets; foods are more than just collections of nutrients. • Nutrients interact differently, depending on the food matrix • Methods of food processing, preparation and cooking influence the nutritional value of foods. • Foods and diets have cultural, ethnic, social and family aspects that individual nutrients themselves do not have, UNESDA therefore considers it unfeasible that food-based dietary guidelines could be adapted on the basis of the general principles in establishing nutrient profiles intended for the specific purpose of determining whether a foodstuff should bear a health and/or nutrition claim on its label.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Unilever	4. Scientific process in setting FBDG	Line 361 Improving the nutrient composition of (processed) food products currently on the European market by e.g. reducing less healthy nutrients and/or increasing those regarded beneficial to health should also be considered as a useful approach to improve population nutrient intakes, next to FBDG. This can be stimulated by labelling initiatives, such as a health logo (Choices).
Unilever	4. Scientific process in setting FBDG	lines 379-383 To some groups in the population, however, it is challenge to achieve an adequate intake of fruits and vegetables. Minidrinks (“shots”) prepared from significant amounts of fruits and vegetables (e.g. Knorr Vie) may be a suitable means to replenish their specific needs.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Unilever	5. Implementation and evaluation of FBDG	lines 788-795 The impact of a specific FBDG policy on a population's diet can be further enhanced by improving the nutrient composition of the (processed) food products available to the consumer. Rather than changing habitual intake patterns, this aims at reducing the intake of nutrients associated with chronic disease risk such as saturated fatty acids, trans fatty acids, sodium, and added sugar by reducing these nutrients in the food products themselves. Recently, a method was proposed for evaluating and improving the nutritional composition of a wide range of food products (Nijman et al, 2007). This approach triggered the start-up of the Choices programme which is a world-wide initiative set up to make the healthy choice the easy choice to the consumer (http://www.choicesinternational.org/index.php?option=com_frontpage&Itemid=1). It has introduced a simple front-of-pack stamp on food products that passed an evaluation against a set of qualifying criteria based on international dietary guidelines. Those criteria are periodically reviewed by an independent international scientific committee made up of leading scientists. Nutrients currently covered include saturated fat, trans fat, sodium, added sugar and dietary fibre (http://www.choicesinternational.org/index.php?option=com_content&task=view&id=31&Itemid=54). Food based dietary guidelines from 21 countries across the world form the basis of the underlying criteria. The Choices stamp is: - Simple, one stamp for many products, easily recognisable - Credible, qualifying criteria developed by independent, leading scientists - Open, any food, retail or catering company can participate - International, a global initiative, applicable to all food products and beverages Reference C.A.J. Nijman, I.M. Zijp, A. Sierksma, A.J.C. Roodenburg, R. Leenen, C. van den Kerkhoff, J.A. Weststrate, G.W. Meijer. A method to improve the nutritional quality of foods and beverages based on dietary recommendations. Eur J Clin Nutr 2007;61:461-71.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Unilever	5. Implementation and evaluation of FBDG	lines 803-804 Reducing the content of nutrients associated with chronic disease risk in food products available to the consumer e.g. through the Choices initiative (http://www.choicesinternational.org/index.php?option=com_frontpage&Itemid=1) can further enhance the impact of FBDG. A simple front-of-pack logo such as the Choices stamp can help consumers make healthy choices and seems to work as well for the less health conscious and lower-educated, and across countries (Feunekes et al, 2008). Reference G.I.J. Feunekes, I.A. Gortemaker, A.A. Willems, R. Lion, M. van den Kommer. Front-of-pack nutrition labelling: testing effectiveness of different nutrition labelling formats front-of-pack in four European countries. Appetite 2008;50:57-70.
Unilever	5. Implementation and evaluation of FBDG	lines 856-863 Reducing the content of nutrients associated with chronic disease risk in food products available to the consumer e.g. through the Choices initiative (http://www.choicesinternational.org/index.php?option=com_frontpage&Itemid=1) should be taken into account in assessing the compliance to FBDG and evaluating the impact on individual dietary intake data. The impact that the Choices approach could have on improving nutrient intakes at the population level is currently being estimated by modelling existing national food consumption data (Roodenburg et al, in preparation).
University of Surrey on behalf of the EURRECA Network of Excellence	2. Rationale for FBDG	line 253-259 The relationship between FBDGs and other policy options needs to be transparent, i.e. the process through which policies have been developed and how FBDGs have been used in this process.
University of Surrey on behalf of the EURRECA Network of Excellence	3. General principles for establishing FBDG	line 300-302 One would ideally like to test the hypothesis that basic guidelines are less effective than country specific guidelines. line 306-310 Policy development is a social process that each party brings their own perspectives, values, histories and goals into. Understanding who the stakeholders are and how they interact will constitute an important building block in policy development. In recent years the ethos of public and stakeholder engagement has become increasingly embedded in governance at all levels across the EU. It is now considered an integral aspect of the European

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		governance agenda and the associated drive for democratic renewal (e.g. EC, 2001; EC 2002; EC, 2006). A series of policy documents, research initiatives and institutional changes reflect the emphasis upon evidence-based policy making, openness and transparency, and greater public and stakeholder involvement. Such involvement is thought to ultimately lead to better decisions by increasing the Commission's responsiveness to publics' needs, which in turn serves to improve public service delivery. It also is thought to contribute to democratic renewal as greater accountability leads to increased legitimacy of, and public trust in, governing institutions. The White Paper on Governance (EC, 2001) reinforced the culture of consultation and dialogue in the EU by specifying the need for, and the means of, achieving better mechanisms of public and stakeholder involvement. The EU Green Paper on Transparency Initiative (EC, 2002) further developed the general principles and minimum standards on consultation in order to achieve greater consistency in public and stakeholder involvement and more meaningful participation. It stated that "openness and accountability are important principles for the conduct of organisations when they are seeking to contribute to EU policy development. It must be apparent which interests they represent and how inclusive that representation is." (2002:17). Thus, achieving representativeness is a key challenge in the drive for democratic renewal, as it is seen to be instrumental in reducing "the risk of the policy-makers just listening to one side of the argument or of particular groups getting privileged access" (2002:5). This means that "the target groups of relevance for consultation need to be identified on the basis of clear criteria" (EC, 2002:5). What these criteria are however, is subject to an ongoing academic and policy debate, which reflects the multifaceted nature of the construct of representativeness – both in terms of its theoretical underpinnings as well as the way in which the term is used in the context of public and stakeholder involvement. European Commission. 2006. Green Paper: European Transparency Initiative. COM 2006 194 final, 3 May. European Commission. 2002. Communication from the Commission: Towards a Reinforced Culture of Consultation and Dialogue – general principles and minimum standards of consultation of interested parties by the Commission. COM 2002 704 final, 11 December. European Commission. 2001. European Governance: A White Paper. COM 2001 428 final, 25 July.
University of Surrey on behalf of the EURRECA Network of Excellence	4. Scientific process in setting FBDG	Section 4.1 (lines 332-431) This process does not need to happen at national level, much of this activity could be done for example at national level. Given that nations might tackle the tasks of setting FBDGs at different times, it is of course good practice to establish what the current state of play is in terms of evidence,

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University of Surrey on behalf of the EURRECA Network of Excellence	4. Scientific process in setting FBDG	Section 4.6 (lines 755-766) It is also important to take into account psycho-social factors and cultural practices into account. One needs to draw on the social-scientific evidence base to understand consumer behaviour. Section 4.7 There is a need for a stronger evidence base with regard to consumer awareness, understanding and use of FBDGs in whatever form they exist, text, graphical. See for example this recent publication: Albert J (2007) Global Patterns and Country Experiences with the Formulation and Implementation of Food-Based Dietary Guidelines. Ann Nutr Metab 2007;51 (Suppl. 2):2-7 The publication concluded that there are four main areas for improvements are: (1) FBDG are mainly developed and used within the health sector, involvement of the agriculture and education sectors is needed; (2) few counties communicate to widely reach the public; (3) many messages do not motivate changes in behavior, and (4) the application of FBDG in setting policies not sufficient received attention.
University of Surrey on behalf of the EURRECA Network of Excellence	5. Implementation and evaluation of FBDG	It would be helpful to have more guidance regarding the implementation, monitoring and evaluation of FBDGs. One measure could include how imbedded FBDGs are in policy.
University of Surrey on behalf of the EURRECA Network of Excellence	5. Implementation and evaluation of FBDG	It would be useful to collect further data on currently used FBDGs to add to the data already collected and described in this document. Data should focus on both the development and effectiveness of these guidelines.
World Sugar Research Organisation	1. Introduction	lines 32-33 WSRO strongly supports the approach suggested in this draft opinion that FBDG should be focussed on diet-disease relationships of particular relevance to a specific population group, rather than attempting to create universal guidelines covering all nutrients and all population groups. In defining popluation groups attention should be directed towards groups with homogeneous responses to the chosen dietary manipulations rather than geographic or racial groupings. To be effective, therefore, FBDG must take account of the interactions between diet and genetics (which may not segregate tidily into countries or even racial groupings), rather than seeking to create FBDG to suit particular political or geographic administrative boundaries.

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World Sugar Research Organisation	1. Introduction	lines 36-42 In designing FBDG that will be practically useful, and command the respect of the intended target audiences, it is important to focus on diet-health relationships that can be supported by good quality evidence, rather than hypothetical problems that have not, in fact, been shown to occur (or occur so rarely that population FBDG are not an appropriate response). In this regard, WSRO would question the inclusion of sugars in the list of "nutrients that might be consumed in excess". That there is no persuasive evidence that this occurs widely in practice is shown by the failure of the Institute of Medicine review (2002)to establish an Upper Level for sugars intake. Clearly, no consistent evidence could be found that harm had resulted from the consumption of sugars at any of the wide range of intakes identified in the US population. If there was such evidence, an UL could have been established. Thus over-consumption of sugars falls among the very large number of hypothetical nutritional problems that have yet to be shown to occur in practice. The grounds for "concern" that sugars might be consumed in excess rely solely on comparison of the current range of intakes seen in many European popluations with nutrient based guidelines elaborated by some expert groups (such as those cited in WHO Technical Report 916 (2003)). These nutrient based guidelines are opinions that are not based on evidence derived from controlled intervention studies in general popluation groups. In respect to sugars, the WHO Report 916 opinion (and that of several older reports) has selected a numerical target that is entirely arbitrary (since no evidence at all is cited to support the choice of target) and based on a misinterpretation of the evidence relating to dental caries risk. It is therefore unreasonable to identify sugars as a suitable subject for food based dietary guidelines without further evidence that altering sugar consumption will assist any health problem in any European population group. Indeed, the liklihood that discouraging sugars consumption might give rise to unfortunate inbalances in people"s diets cannot be discounted (especially with respect to fat intake). Any intervention to discourage sugars consumption should be preceeded by evidence of effectiveness in reducing at least one real (rather than imaginary) health risk, and moreover, evidence of safety.

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World Sugar Research Organisation	4. Scientific process in setting FBDG	line 432 As mentioned previously, the choice of administrative unit for establishing FBDG should not be "country" since the populations of no European Country are homogeneous and never have been. FBDG must be directed carefully at population groups that will benefit. This means that health/ disease/ nutrient intake data must be sufficiently detailed (and accurate) to allow the clear delineation of population groups that will benefit from any particular FBDG from those that will not benefit, and especially from those that may be disdvantaged by taking the advice offered.
World Sugar Research Organisation	4. Scientific process in setting FBDG	line 442 This sentence should read "....contributed to the top 5 most important known risk factors". The epidemiological analyses that lead to this conclusion are based onthe assumption that the risk can be distributed among known or postulated risk indicators. Since the evidence used is association evidence from observational popluation studies, the possibility of confounding by substantial, but as yet unidentified risk factors, cannot be excluded. Neither low intake of fruit and vegetables, nor obesity have been subject to controlled intervention trials to establish that they are direct (as opposed to covariant) risk indicators. It is important not to repeat the mistakes of the "protein gap" era by assuming that further research is unnecessary because all necessary information for action is already known.
World Sugar Research Organisation	4. Scientific process in setting FBDG	line 474 These are indeed nutrients that might be consumed in excess. But ther are also a large number of others. The selection of relevant nutrients to address through FBDG must be based on evidence or real problems not hypothetical ones. In this list sugars belong to the latter category. There is no persuasive evidence that overconsumption of sugars is a real problem for any significant proportion of any European popluation group.

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World Sugar Research Organisation	4. Scientific process in setting FBDG	line 535 This prioritisation presupposes that a reliable DRV has been established for any nutrient that will be addressed through FBDG. The establishment of a reliable DRV for a nutrient suspected of potentially being consumed in excess relies, in turn, on the establishment (among other things) of a reliable estimate of an Upper Level. Where an UL cannot be established, through lack of evidence of untoward effects, "Recommended intake ranges" should not be used instead, since these are essentially judgements based on informed (but not necessarily reliable) expert opinion. Where an UL cannot be established for a population group there is clearly no need of FBDG for that population group, since the absence of evidence on which to base an estimate of an UL indicates that excessive intake of the nutrient in question is not a sufficiently common problem to merit population-wide FBDG. Individual counselling may still be offered where appropriate, if over-consumption is seen sporadically. This is not a Type 2 error since, in this instance, evidence of harm is the key factor in deciding which nutrients merit FBDG. The absence of such evidence would indicate that the nutrient in question should not be selected for FBDG designed to decrease intake.
World Sugar Research Organisation	4. Scientific process in setting FBDG	line 572 - 600 This approach is entirely reasonable but it should be noted that the recommended maximum intake of macronutrients considered to be consumed in excess is most commonly expressed as a proportion of overall food energy intake. So any change in the intake of that macronutrient will inevitably influence the propotion of energy consumed from other sources. So, care must be taken not to cause consumption of another macronutrient to rise too far by cutting intake of the targetted macronutrient. thsi may have already happened with protein intake in babies and young children, as a result of over-zealous reductions in fat and sugar intake. Similarly, the intake of a targeted macronutrient may be significantly influenced by changes in another macronutrient. This may offer a practical means of influencing consumption of the targetted macronutrient indirectly, provided the other macronutrient would not, as a result. be over-consumed. An example of this approach has been demonstrated with sugar intake. Reduction in sugar intake tends to increase fat as a proportion of overall energy intake (rather than protein or starch, both of which might equally be affected). An increase in sugar intake tends to push fat consumtion down.
World Sugar Research Organisation	4. Scientific process in setting FBDG	line 607-609 This comment (which echoes a similar reservation with regard to dietary fibre expressed by the recent FAO/WHO Update on Carbohydrates (2007) should caution against planning major interventions to change the diets of whole populations through FBDG (or any other means) without clear intervention study evidence. The current over-relience on observational epidemiology is not, on its own, a sound basis for action.

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World Sugar Research Organisation	4. Scientific process in setting FBDG	line 615 compred with line 454 It is noteworthy that Cyprus and Greece have the highest availability of fruit and vegetables of the Eyropean region, while they also have among teh highest prevalence of obesity. This should caution agaisnst the assumption that increasing availability or consumption of fruit and vegetables will alone materially influence obesity rates.
World Sugar Research Organisation	4. Scientific process in setting FBDG	lines 437-439 These estimates of DALY lost raise some important issues. If the combined impact of all inappropriate diets are so low, then establishing the results of any intervention to change particular aspects of dietary behaviour will rely on extremely accurate and regular monitoring of dietary changes and of the health experience of the populations in question. It will also be extremely difficult reliably to correct for the influences of confounding factors, especially advances in medical care. While these technical issues are impotant they should not be allowed to prevent the careful assessment of the results of dietary interventions, since good evidence will be required to justify the expense of intervention, both in direct costs and in the consequent economic costs of dietary change to major sectors of the food industry (e.g. dairy).
World Sugar Research Organisation	4. Scientific process in setting FBDG	lines 706 following (section 4.6) While modelling is a useful and necessary step in the process of testing and optimising FBDG, it is not sufficient. Modelling cannot entirely anticipate how large numbers of individuals may react to any particular FBDG of which they become aware (including, of course, people for whom the FBDG were not designed). It is essential that field testing with real people is included in the testing protocol. The subjects involved in such testing must include examples of the intended target groups but also examples of subjects who may be influenced by the FBDG despite not being intended targets.